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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/900,559 07/25/97 CHENG

S 226/242

022249
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HM22/0121

EXAMINER

HINES, J

ART UNIT

PAPER NUMBER

1641

DATE MAILED:

01/21/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/900,559

Applicant(s)

Cheng et al.

Examiner

Ja-Na Hines

Group Art Unit

1641



☒ Responsive to communication(s) filed on Nov 15, 1999

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 10-20 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 10-20 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed November 15, 1999 have been fully considered but they are not persuasive. Claims 10-11, 13-15 and 17-20 is rejected under 35 U.S.C. 102(b) as being anticipated by Imrich et al.(US Patent 5,415,994) is maintained.

. Applicant argues that Imrich et al., fails to teach a separate sample chamber not in flow communication with the test strip. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the claims of the instant application do not recite any structural limitations with respect to the placement of the sample chamber) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims.

Applicant further argues that Imrich et al., teaches additional limitations, however these aspects of Imrich et al., are not excluded from the claims. The term "comprising" is read as open language and can therefore include any additional features taught by Imrich et al.

Applicant also argues that Imrich et al., does not teach inserting the sampling into the receiving region without further manipulation, however Imrich et al., teaches the extraction chamber allows for pretreatment of a sample generally presented on a swab (col. 3 lines 60-66). The extraction solution may added to the chamber, and may be treated with an acidic extraction solution such as nitrous acid to expose Group A streptococcus specific antigen (col. 4 lines 15-

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20). The extraction solution may contain nitrous acid which is relatively unstable, as a result, to generate nitrous acid, sodium nitrite and acetic acid must be mixed immediately before initiation of the antigen extraction process (col. 8 lines 50-63). The sample receiving zone may contain a neutralizing agent which will neutralize the extraction solution and may be placed on the surface of the sample receiving zone (col. 5 lines 1-7). Therefore the sample is presented in the chamber and there is no additional manipulation.

2. Applicant again refers to the Declaration of Richard H. Schwartz under 37 CFR 1.132 filed May 10, 1999. However the Declaration is still insufficient to overcome the rejection of claims 10-20 based upon Imrich et al., alone or in combination with Bogart et al., because it refers to OSOMTM system and not to the individual claims of the instant application. The declaration makes references to the OSOMTM's type of housing and its overall sensitivity, however those features are not relevant to the claims of the instant application. There is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims. See MEP. § 716. Therefore, again, the Schwartz Declaration is not persuasive.

3. Claims 12 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Imrich et al., in view of Bogart et al., is maintained. Imrich et al., has been discussed above.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the

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teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In this case, it would have been obvious to one of ordinary skill in the art to optimize the experimental parameters and reagents of the method of Imrich et al., by selecting such conventional components for generating nitrous acid and times of extraction as taught by Bogart et al., where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill. No more than routine skill is involved in adjusting the amount or concentration of a claimed component in a process to suit a particular starting material in order to achieve the results taught in the prior art.

Applicant also argues about the spatial separation of the assay chamber. In response to applicant's argument that the references fail to show these features of applicant's invention, it is noted that the features upon which applicant relies i.e., the spatial relationship of the assay chamber are not recited in the rejected claims, nor do the claims recite any type of spatially relationship or placement of the assay chamber. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines



January 13, 2000



JAMES C. HOUSEL 1/18/00
SUPERVISORY PATENT EXAMINER